REMARKS

Claims 1-12 are pending in the present application and stand rejected. Claim 1 has been amended herein. No new matter is added. See the application as a whole and in particular, paragraph 9, for support.

Claims of the present application are rejected as anticipated by Chretien, U.S. Patent No. 6,001,799 (hereinafter "Chretien"), Goldstein, U.S. Patent No. 5,585,352 (hereinafter "Goldstein"), Knutsen, international application WO 98/35696 (hereinafter "Knutsen") and Rudolph, U.S. Patent Publication 2005/0049191 (hereinafter "Rudolph"). "A claim is anticipated only if each and every claim element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (*citing Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628-631 (Fed. Circ. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Id.* (*citing Richardson v. Suzuki Motor Co.*, 868 F.2d 1226-1236 (Fed. Cir. 1989).

The Chretien patent does not relate to a method of treating or preventing Aspergillus infection or even mention Aspergillus or any other fungal infection. Chretien does not connect hepatitis C treatment to fungal infection or to immunocompromised patients. Chretien therefore lacks any teaching or even a suggestion of a method of treating Aspergillus, and there is no indication whatsoever that the HCV treatment of Chretien (for HCV-infected persons who do not respond to interferon treatment) inherently (necessarily) prevents Aspergillus infection. Therefore, the Chretien reference does not anticipate the claims of the present application.

The Goldstein patent also does not relate to a method of treating or preventing Aspergillus infection or even mention Aspergillus or any other fungal infection. Goldstein does not connect treatment of septic shock to fungal infection or to immunocompromised patients. Goldstein therefore does not anticipate the claims presented here because it does not provide any indication that the septic shock

treatment of Goldstein correlates in any way to Aspergillus infection or an immunocompromised state, much less that treatment of septic shock as taught by Goldstein necessarily results in treatment or prevention of aspergillosis. Goldstein does not teach the claimed method expressly or inherently.

The Knutsen reference teaches a method of promoting stem cell development to mammals in need thereof. Such mammals include, but are not limited to, mammals that are T cell–or stem cell-deficient or who are affected with an immunodeficiency disease. See paragraph bridging pages 5-6. The teachings of Knutsen clearly indicate and teach the skilled artisan to promote stem cell differentiation to any mammal in need of this treatment. This is not confined to mammals which are immunocompromised. The Knutsen reference does not teach a method that necessarily results in what is claimed. Therefore Knutsen does not teach the method of the claims, expressly or inherently, and does not anticipate the claims here.

The Rudolph application teaches a method of delivering thymosin alpha 1 to maintain an immune stimulating amount of this peptide for at least about 6 hours (claim 1). Rudolph does not teach a method of treating or preventing Aspergillus infection and does not even mention any fungal infection. Rudolph mentions treating patients with hepatitis and cancer patients, and does not correlate all of such patients with an immunocompromised state or with fungal infection. The treatment of Rudolph does not necessarily result in the claimed method. Rudolph therefore cannot anticipate the claims here.

Claims 1-12 are rejected as obvious over Wingard, Bone Marrow Transplant. 19:343-347, 1997 (hereinafter "Wingard") in view of Knutsen, discussed above. Wingard is cited as teaching use of amphotericin B for Aspergillus infections in bone marrow transplant patients. Knutsen is cited as teaching thymosin alpha 1 treatment of bone marrow transplant patients. The Office considers it obvious to co-administer these compounds to treat/prevent fungal infection with amphotericin B while stimulating

hematopoiesis with thymosin alpha 1. Applicant traverses this rejection.

Wingard presents a study of a lipid complex injectable formulation of amphotericin B, a broad spectrum antifungal drug. Some of the patients enrolled in the study were bone marrow transplant recipients who were evaluated for efficacy and safety of the treatment. Some of these patients had aspergillosis (page 345, left column, lines 28-29) and of those patients some responded to the treatment. Wingard does not discuss or even mention thymosin alpha 1 and does not suggest or hint that thymosin alpha 1 has an antifungal effect.

Knutsen, as discussed above, teaches that thymosin alpha 1 can be used to promote stem cell development in mammals. Knutsen does not discuss or even mention fungal infection and certainly does not teach or suggest any antifungal activity for thymosin alpha1.

Claim 1 of the present application is directed to a method of treating or preventing Aspergillus infection in a mammal by administering an antifungal amount of thymosin alpha 1. Nothing in the cited art even hints that thymosin alpha 1 should or could be used to treat aspergillosis or what an antifungal effective treatment with thymosin alpha 1 would be. Knutsen does not teach or suggest an antifungal treatment with thymosin alpha 1 and Wingard teaches using amphotericin B, not thymosin alpha 1, for fungal infection. The Office furthermore has pointed to nothing either cited references or anything in the art generally that even hints that persons of skill would assume that thymosin alpha 1 has antifungal activity.

Even the combination of Wingard and Knutsen, if one of skill would treat a patient with amphotericin B to treat/prevent fungal infection and also would happen to treat that same patient with thymosin alpha 1 for promoting stem cell development, does not teach or suggest claim 1 here, since nothing indicates that thymosin has this activity. The skilled artisan could not logically conclude that thymosin alpha 1 can treat fungal infection merely because it may sometimes have been administered while amphotericin

B is being administered to perform that function. In summary, nothing in any of the cited art teaches or suggests to the artisan the method of claim 1, since nothing hints that thymosin alpha 1 treats or prevents Aspergillus infection; nothing hints that thymosin alpha 1 has any antifungal activity, when administered alone or when administered with amphotericin B.

In summary, the invention here is a method of treating/preventing Aspergillus infection with thymosin alpha 1. Nothing in the art teaches or suggests this. The art teaches that amphotericin B is required to treat fungal infection, which is a teaching away from the invention of claim 1. The mere fact that the treatment of Wingard and the treatment of Knutsen can be combined does not render this invention obvious unless the result that thymosin alpha 1 possesses antifungal activity would have been predictable to a skilled person. Since nothing even hints at this result, the skilled person would not have been able to predict the method of claim 1, and this claim is not obvious.

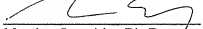
Even the Office recognizes the unpredictability of the method of claim 1 in view of the art, because one "would reasonably expect the two drugs would function as they are known to in the art – $T\alpha_1$ would stimulate hematopoiesis and amphotericin B would treat/prevent fungal infection." Office Action, page 4, lines 6-8. Here, the independent claim is directed to a method where thymosin alpha 1 is administered in an antifungal effective amount to treat or prevent Aspergillus infection, not to stimulate hematopoiesis as was taught in the art. Therefore, the Office appears to have shown only that it is obvious to treat aspergillosis with amphotericin B.

Since the Office is not able to establish any teaching or suggestion in the art with

respect to the method of claim 1 or any reasonable expectation of its success, claim 1 cannot be obvious over the cited art. All the remaining claims are dependent on claim 1 and therefore also cannot be obvious over this art. Applicant therefore requests withdrawal of this rejection.

Applicant requests withdrawal of the rejections and reconsideration of the present application at this time.

Respectfully submitted,

By: 

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